PERSONNEL MANUAL

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| Subject Title: Applicant Drug Screening Policy | Issued by: Employee Services | | | |
| Reference(s): Mayor's Dir. 89-4 (6/19/89), Mayor's Dir. 89-8 (10/5/89), Personnel Cir. No. 7-92 (6/23/93) | | | | |
| <pre>Purpose(s): To establish a policy to screen all selectees for City jobs for drugs.</pre> | | | | |

I. PURPOSE

The City and County of Honolulu (hereinafter "Employer") recognizes that because the use and/or abuse of drugs and/or substances may adversely affect an employee's health, safety and job performance as well as the health and safety of his/her coworkers and members of the general public, appropriate drug screening tests may be implemented to aid the Employer in identifying prospective employees who use and/or abuse such drugs or substances. Properly conducted, such tests will lead to a safer work place.

II. DEFINITIONS

- A. <u>Substance/Drug:</u> 1) Any intoxicating liquor. 2) Any intoxicating compound. 3) Any drug, substance, or immediate precursor listed on Schedule I or II of the State of Hawaii's or the Federal government's Controlled Substances Act.
- B. <u>Personnel Director</u>: The Director of Personnel of the City and County of Honolulu.
- C. <u>Department</u>: The department head or designee.

III. COVERAGE

This policy covers all prospective employees except where the language clearly indicates otherwise.

IV. DRUG SCREENING PROGRAM

A drug screening program applicable to all applicants entering Civil Service is hereby established. The drug screening program is designed to establish and create a safe working environment

PERSONNEL MANUAL

C 28.2

for the protection of all employees; protect members of the public who use or avail themselves of the Employer's facilities or services; and protect the public health, safety and welfare. As part of the drug screening program, the Employer may administer appropriate drug screening tests to all applicants as part of the applicant's pre-entry medical examination.

V. <u>EMPLOYER RESPONSIBILITIES</u>

As the coordinator of the Drug Screening Program the Employer may assume the following duties and responsibilities:

- 1. Establish and approve procedures which must be followed by the approved laboratory facility.
- Determine the substances for which testing shall be conducted.
- 3. Determine the method of testing which shall be used for each substance to be tested.
- 4. Administer and/or coordinate with the approved laboratory facility all drug screening tests required under this policy.
- 5. Receive all test results for the above tests and transmit the results to the appropriate parties.

The Personnel Director is responsible for the overall management of the Drug Screening Program including, administering the program, establishing procedures and amending the policy as needed.

VI. TEST PROCEDURES

All drug screening tests shall be conducted in a manner consistent with the provisions set forth below:

When a department notifies an applicant to report for a preentry examination the applicant shall report for and undergo the examination as scheduled. Applicants are required to take a photo ID card to the examination site when they report for their examination. Failure to appear for the examination without adequate reasons may result in the applicant being deemed to

C 28.3

have failed the examination. If the urine is to be collected as part of the test, the urine shall be obtained and tested in a manner consistent with the procedures set forth in the Attachment.

VII. REFUSAL TO SUBMIT TO TESTING

The Employer need not select any applicant who refuses to submit to a test for that position and may remove his/her name from the eliqible list for that position for the duration of the list.

VIII. TEST RESULTS

The Employer's physician shall receive all negative and confirmed positive test results for all applicants who undergo a pre-entry medical examination.

- 1. The Employer's physician shall transmit a report on each confirmed positive result to the department which requested the examination as set forth in the Attachment.
- 2. The department shall take appropriate action based on the results as set forth in this policy. The test results are highly confidential and shall only be disclosed to those who must know.

IX. CONFIRMED POSITIVE RESULTS

Applicants who have a confirmed positive test will not be selected for the position, and their names will be removed from any eligible lists they are on at the time for the duration of the lists.

The Employer will reject the application of an applicant who has a confirmed positive pre-entry test result for a period of six months after the test. After the six-month period the application may be accepted. However if the applicant who had a positive pre-entry test result, or any former City employee who had a positive test result and was not cleared to return to work, is selected for a position the City Physician will determine if there is sufficient evidence to indicate that the applicant is no longer an illegal user of drugs. The pre-entry medical and drug test will beheld in abeyance pending this determination. If there is insufficient evidence it will be

PERSONNEL MANUAL

C 28.4

determined that the applicant does not meet City requirements, the pre-entry medical and drug test will not be conducted, and the applicant's name will be removed from the eligible list from which he/she was selected for the duration of the list.

Applicants who have a confirmed positive test result may submit applications before the end of the six-month period and/or may have their names restored to the eligible lists from which they were removed if the City Physician determines that there is sufficient evidence to indicate that the applicant is no longer an illegal user of drugs. (The City Physician may require that the applicant undergo a drug test to aide the Physician in making the determination.) If such a determination is made: 1) the applicant shall be permitted to submit subsequent applications; 2) the applicant's name shall be restored to the eligible lists from which he/she was removed provided such lists are still active and the applicant meets all other necessary requirements; 3) if the applicant is subsequently selected for a position, the above provision requiring that a determination be made that the applicant is no longer an illegal user before the medical or drug test is conducted shall be considered to have been met.

X. SAVINGS CLAUSE

Should any part of this Policy be rendered or declared invalid by reason of any existing legislation or by a decree of a court of competent jurisdiction, such invalidation of such part or portion of this Policy shall not invalidate the remaining portions thereof, and they shall remain in full force and effect.

PERSONNEL MANUAL

C 28.5

INTRODUCTION

This document represents the Employer's "Scientific and Technical Guidelines for Drug Screening Programs" as provided for in the Drug Screening Policy.

These guidelines address the mandatory scientific and technical requirements of drug testing procedures, including: collection of specimens, laboratory analysis, and the transmittal and interpretation of results, which must be followed by the Employer or its contractors in conducting drug screening tests pursuant to the Drug Screening Policy.

These guidelines are effective immediately; however, departments which currently have an operating drug screening program may continue with their programs.

PERSONNEL MANUAL

C 28.6

SCIENTIFIC AND TECHNICAL REQUIREMENTS

I. THE DRUGS

As part of the Drug Screening Policy, the Employer will determine which drugs will be included in the screening program . The definition of "drugs or substances" as set forth in the Policy includes but is not limited to those drugs or substances contained in Schedule I or II of the State or Federal Controlled Substances Act (CSA). These schedules cover hundreds of drugs, but it is obviously not practical to test for all of them.

This document presents specific information on the drugs most likely to be included in the drug screening program (i.e., marijuana, cocaine, opiates, amphetamines, and PCP). The personnel director may include any additional drugs (or classes of drugs) in the screening procedures.

II. DEFINITIONS

ALIQUOT: A portion of a specimen used for testing. An appropriate amount is transferred into a labeled test tube.

APPROVED LABORATORY FACILITY: A laboratory facility approved by the Employer which has the facility and capability of performing the initial and confirmation tests for each drug or metabolite listed in Schedules I and II of the State and Federal Controlled Substance Act. The approved medical facility must operate consistently with any applicable licensing requirements of the State of Hawaii or of the state in which it operates. The approved laboratory facility may either be an Employer facility or a facility owned by an Employer's contractor.

AUTHORIZED PERSONNEL: Individuals determined by the approved laboratory facility and the Employer to have a need for access to areas used for the receiving, testing, and storage of urine specimens; further, this definition shall include laboratory supervisors and authorized officials of the Employer with the authority to sign for and take control of urine specimens through the use of the chain of custody format.

CHAIN OF CUSTODY: Refers to the methodology of tracking specified materials and/or substances for the purpose of maintaining

PERSONNEL MANUAL

C 28.7

control and accountability from initial collection to final disposition for all such materials and/or substances and must provide for accountability at each stage in handling, testing, storing specimens, and reporting test results.

CONFIRMATION TESTING: A second procedure (test) used to demonstrate the presence of specified drugs of abuse or their metabolites in given urine specimens. This test must be different in format and chemical theory from that of the initial testing procedure utilized. Currently the gas chromatography/mass spectrometry procedure is the only acceptable method.

INITIAL TEST: A sensitive, rapid, and inexpensive immunoassay screen to eliminate "true negative" specimens from further consideration.

INTRALABORATORY CHAIN OF CUSTODY: Procedures used by the approved laboratory facility to maintain control and accountability from the receipt of urine specimens until testing is completed, results reported, and while specimens are in storage.

MEDICAL REVIEW OFFICIAL: The Medical Review Official (MRO) is responsible for receiving laboratory results generated from the drug screening program. This officer will be a licensed physician with knowledge of substance abuse disorders and the appropriate medical training to interpret and evaluate all positive test results together with the applicant's medical history and any other relevant biomedical information.

SAMPLE RUN: An analytical run is a group of specimens consisting of standards, quality control specimens, and unknowns which are processed and measured sequentially or simultaneously under a standard set of conditions. The analytical run is designed in such a way that quality control specimens can be related to a defined group of unknown specimens.

SPECIMEN: A sample of human urine, between 30 and 60 milliliters in volume, to be confined in a shatter-resistant, sealed, and marked container.

III. SPECIMEN COLLECTION PROCEDURES

A. COLLECTION SITE

PERSONNEL MANUAL

C 28.8

The collection site is a place where specified applicants present themselves for the purpose of providing urine specimens to be analyzed for drugs. The collection site may be at an Employer facility or at an approved laboratory facility.

The site must possess all necessary personnel, materials, equipment, facilities, and supervision to provide for the collection, security, temporary storage, and transportation (shipping) of urine specimens to an approved laboratory facility.

The collection site, although serving a separate function, may be on the approved laboratory facility's premise or at other locations approved by the Employer.

Procedures must provide for the collection site to be secure. Chain of custody forms must be properly executed by authorized collection site personnel upon receipt of specimens. The handling and transportation of urine specimens from one authorized individual or place to another must always be accomplished through the use of chain of custody procedures. No unauthorized personnel shall be permitted in any part of the collection site where urine specimens are collected or stored.

B. COLLECTION PROCEDURES

Procedures for the collection of urine specimens must, to the extent possible, allow the individual to provide the urine sample in the confines of a toilet stall or urinal, outside of the direct observation of the collection site personnel, unless the department has reason to believe that a particular individual may alter or substitute the specimen to be provided. The Employer's physician must take precautions to ensure that a urine specimen has not been adulterated or diluted during the collection procedure and that all information on the urine bottle and in the logbook can be identified as belonging to a given individual. To ensure the employee's privacy and that unadulterated specimens are obtained, the following procedures outline the minimum precautions that shall be taken during the collection of urine specimens by either the employer, if the collection is handled by the Employer's Physician, or by the approved laboratory facility employees, if the collection is handled by a contractor:

1. At the collection site, toilet bluing agents shall be placed in the toilet tanks, wherever possible, so the reservoir of water

PERSONNEL MANUAL

C 28.9

in the toilet bowl and tank always remains blue. There should not be any other source of water $(\underline{e.g.}, \text{ shower}, \text{ sink})$ in the enclosure where urination occurs.

- 2. Upon arrival at the collection site the individual shall present some type of photo identification. If the individual does not have proper identification, the individual's thumb print shall be taken and the person shall be tested. If the individual fails to appear at the assigned time the requesting department shall be informed and shall take appropriate action.
- 3. The individual will remove any unnecessary outer garments (e.g., coat, jacket) that might conceal items or substances that could be used to tamper with or adulterate his/her urine specimen. Also, all personal belongings (e.g., purse, briefcase) must roman with the outer garments; the individual may, however, retain his/her wallet. The collection site person shall note any unusual behavior or appearance. The collection site person shall hand the individual a specimen container. The specimen container label shall include the date, the individual's name or confidential code number, and any other identifying information provided and/or required by the department. The collection site person shall enter the identifying information in a log. The individual shall sign the log next to the identifying information.
- 4. The individual shall wash and dry his/her hands prior to urination.
- 5. After washing hands, the individual shall remain in the presence of the collection site person and not have access to water fountains, faucets, soap dispensers, or cleaning agents.
- 6. The individual may provide his/her specimen in the confines of a toilet stall, urinal or otherwise partitioned area that allows for either direct or indirect observation by the collection site personnel.
- 7. If the individual elects to provide his/her specimen in the confines of a toilet stall, urinal, or partitioned area out of the direct observation of the collection site personnel, the following procedures should be followed:

Females: A female collection site person should accompany the

C 28.10

individual into the rest room area. The collection site person will insure that the toilet water has been treated with the toilet bluing agent. The individual will void into specimen container. The individual shall not flush the toilet. The collection site person remains in the rest room but outside the toilet stall until the urine specimen is collected and the filled specimen container is handed to the collection site person by the individual.

Males: A male collection site person should accompany the individual into the rest room area. The collection site person will insure that the toilet water has been treated with the toilet bluing agent. The individual will void into the specimen container and shall not to flush the toilet. The collection site person remains in the rest room but outside the stall until the urine specimen is collected and the filled specimen container is handed to the collection site person by the individual.

- 8. Upon receiving the specimen from the individual, the collection site person will determine that it contains at least 30-60 milliliters of urine. If there is not sufficient urine in the container, the specimen is destroyed and a new sample of urine should be collected. The individual may be given reasonable amounts of liquid (e.g., a glass of water). If an individual fails, for any reason, to provide the necessary specimen the requesting department shall be informed and shall take appropriate action.
- 9. After the specimen has been provided and submitted to the collection site person, the individual may wash his/her hands.
- 10. Immediately after collection, collection site personnel shall, in the presence of the individual, measure the temperature of the specimen and conduct an inspection to determine the specimen's color and signs of contaminants. Any unusual findings resulting from the inspection must be included on the chain of custody form. The time from urination to delivery of the sample for temperature measurement is critical and in no case should exceed four (4) minutes. If the temperature of the specimen is outside the range of 32.5 37.7NC / 90.5 99.8NF, then this difference gives rise to reasonable suspicion of adulteration/substitution, and another specimen should be collected under direct observation and both specimens forwarded

C 28.11

to the laboratory. Any specimen suspected to be adulterated should always be forwarded for testing. When reasonable suspicion is established, the second specimen must be obtained under direct observation.

- Both the individual being tested and the collection site person should keep the specimen in view at all times up to its being sealed and labeled. The collection site person will insure that the identification label is securely on the specimen container and place the tamper-resistant seal over the specimen container
- 12. The collection site person shall complete the appropriate chain of custody form.
- The urine specimen and chain of custody form are now ready for 13. shipment. If the specimen is not immediately prepared for shipment, it must be appropriately secured during temporary storage.

NOTE: PROCEDURES, IT IS ESSENTIAL THAT THE URINE SPECIMEN AND CUSTODY DOCUMENTS BE UNDER THE CONTROL OF THE INVOLVED COLLECTION SITE PERSON. IF THE INVOLVED COLLECTION SITE PERSON MUST LEAVE HIS/HER WORK STATION MOMENTARILY, THE SPECIMEN AND CUSTODY FORM MUST BE TAKEN WITH HIM/HER OR MUST BE SECURED. AFTER THE COLLECTION SITE PERSON RETURNS TO THE WORK STATION, THE CUSTODY PROCESS WILL CONTINUE. THE COLLECTION SITE PERSON IS LEAVING FOR AN EXTENDED

WHILE PERFORMING ANY PART OF THE CHAIN OF CUSTODY

PERIOD OF TIME PRIOR TO LEAVING THE SITE, THE SPECIMEN SHOULD BE PACKAGED FOR MAILING.

C. COLLECTION CONTROL

Collection site personnel shall always attempt to have the container or specimen bottle within sight before and after the individual has urinated. The containers shall be tightly capped, properly sealed, and labeled. A chain of custody form approved by the Employer shall be utilized for maintaining control and accountability from point of collection to final disposition of specimens. With each transfer of possession, the chain of custody form shall be dated, signed by the individual releasing the specimen, signed by the individual accepting the specimen, and the purpose for transferring possession noted. Every effort should be made to

PERSONNEL MANUAL

C 28.12

minimize the number of persons handling specimens.

D. TRANSPORTATION TO LABORATORY

After collection of urine specimens, collection site personnel shall arrange to transport the specimens to the approved laboratory facility for testing. If the urine is collected at a place other than at an approved laboratory facility, the specimens shall be placed in appropriate containers (tamper proof bag, specimen boxes or padded mailers) that are securely sealed to eliminate the possibility of tampering. If the urine specimens are mailed, an outer mailing wrapper should be placed around each sealed container. Specimens may be delivered to the approved laboratory facility using either the United States Postal Service, commercial air freight, air express, or may be hand carried. It is not necessary to send specimens by registered mail.

IV. LABORATORY ANALYSIS PROCEDURES

A. RECEIVING/PREPARATION

The approved laboratory facility must be secure at all times. Upon receipt of specimens, the laboratory personnel shall inspect packages for evidence of possible tampering and compare information on specimen bottles with that on chain of custody forms. Any discrepancies shall be properly noted and described. Any direct evidence of tampering shall be reported immediately to the Employer's physician and shall also be noted on the chain of custody form which must accompany all specimens during laboratory possession. If any specimen becomes lost, misplaced, or is improperly delivered, the Employer's physician shall be notified immediately.

Specimens shall not leave the presence and control of authorized receiving personnel until specimens are released to testing personnel or placed in temporary refrigerated storage. Specimen bottles and original chain of custody forms shall be retained within the laboratory area until all analyses have been completed. Aliquots and intralaboratory chain of custody forms shall be used by laboratory personnel for conducting the initial and confirmatory tests.

B. <u>SHORT-TERM REFRIGERATED STORAGE</u>

Specimens that do not receive an initial testing within two days of arrival at the laboratory shall be placed in secure, temporary

C 28.13

refrigeration units. Temperatures shall not exceed six degrees centigrade.

C. SPECIMEN PROCESSING

Approved laboratories will normally process specimens by grouping them into batches. The number of specimens in each batch may vary significantly depending on the size of the laboratory and its work load. When conducting either initial or confirmatory testing, every batch shall contain an appropriate number of standards for calibrating the instrumentation . Both internal and external blind proficiency test samples should appear as ordinary samples to laboratory personnel.

D. INITIAL TEST

The initial testing shall use an immunoassay which meets the requirements of the United States Food and Drug Administration. The following initial cutoff levels shall be used when screening specimens to determine whether negative or positive for these five drugs or classes of drugs:

| | Initial Test Level (ng/ml) |
|-----------------------|----------------------------|
| | _ |
| Marijuana metabolites | 100 |
| Cocaine metabolites | 300 |
| Opiate metabolites | 300 |
| Phencyclidine | 25 |
| Amphetamines | 1000 |

These test levels are subject to change by the Employer as advances in technology or other considerations may permit identification and quantification of these drugs at lower concentrations.

Some specimens may be subjected to initial testing by methods other than immunoassays, where the latter are unavailable for the detection of specific drugs of special concern. These methods are thin layer, high pressure liquid, and/or gas chromatography.

E. <u>CONFIRMATORY TEST</u>

All specimens identified as positive on the initial test shall be finally confirmed using gas chromatography/mass spectrometry

PERSONNEL MANUAL

C 28.14

(GC/MS) techniques. Quantitative GC/MS confirmation procedures at the following cutoff levels shall be used for the following drugs or classes of drugs:

| Confirmatory | Test | Level | (ng/ml) |
|--------------|------|-------|---------|
| | | | |
| | | | |
| | | | |

| Marijuana Metabolite* | 15 |
|-----------------------|-----|
| Cocaine Metabolite** | 150 |
| Opiates: | |
| Morphine | 300 |
| Codeine | 300 |
| Phencyclidine | 25 |
| Amphetamines: | |
| Amphetamine | 500 |
| Methamphetamine | 500 |

*Delta-9-tetrahydrocannabinol-9-carboxylic acid **Benzoylecgonine

These test levels are subject to change by the Employer as advances in technology or other considerations may permit identification and quantification of these drugs at lower concentrations.

Confirmation methods and levels for other drugs tested shall be submitted by any department to the Employer's physician for approval. In the absence of an accepted quantitative GC/MS assay procedure, preference will be given to a confirmation of qualitative identification by means of full-scan GC/MS analysis and quantification by an alternate chromatographic method. All methods shall meet commonly accepted analytical standards.

Proper chain of custody controls shall always be enforced during confirmation testing. Authorized confirmation technicians shall sign the chain of custody forms or laboratory worksheet and be responsible for each urine specimen to be tested. The laboratory shall include sufficient safeguards to ensure that unauthorized personnel are prevented from gaining access to the confirmation laboratory.

F. REPORTING RESULTS AND REPORTS

1. Test Results

Test results shall be reported to the Employer's physician

PERSONNEL MANUAL

C 28.15

within five (5) working days. The report should contain the specimen number assigned to the individual, the approved laboratory facility receipt number, and results of the drug tests. All specimens negative on the initial test or confirmatory test shall be reported by the MRO to the department as negative. Only specimens confirmed positive on all the tests shall be reported by the MRO as positive for a specific drug. Results may be transmitted to the Employer's physician by mail or hand delivery in a manner consistent with the Uniform Information Practices Act (Modified), Hawaii Revised Statutes Chapter 92F. A certified copy of the original chain of custody form, signed by the approved laboratory facility director or approved laboratory facility certifying official, shall be sent to the Employer's Physician. Certified copies of all analytical results shall be available from the laboratory when requested by the individual.

All records pertaining to a given urine specimen shall be retained by the drug testing laboratory for a minimum of two years.

NOTE:

ALL RECORDS, INCLUDING INITIAL TEST RECORDS AND CHROMATOGRAPHIC TRACINGS, SHALL BE RETAINED BY THE LABORATORY IN SUCH A MANNER AS TO ALLOW RETRIEVAL OF ALL INFORMATION PERTAINING TO THE INDIVIDUAL URINE SPECIMENS FOR A PERIOD OF TWO YEARS AFTER COMPLETION OF TESTING OF ANY GIVEN SPECIMEN.

G. LONG-TERM STORAGE

All specimens initially negative and all nonconfirmed positive specimens need not be retained. Specimens confirmed positive shall be retained and placed in properly secured long-term frozen storage for at least 365 days. Within this 365-day period, the Employer may request the laboratory to retain the specimen for an additional period of time. This ensures that the urine specimen will be available for a possible retest during any administrative or disciplinary proceeding. If the laboratory does not receive a request to retain the specimen during the initial 365-day period, the specimen may be discarded.

Long-term storage facilities shall be equipped with secure locks. Access to the long-term storage facility shall be limited to authorized personnel only.

H. RETESTING SPECIMENS

PERSONNEL MANUAL

C 28.16

Should specimen reanalysis be required, the quantitation of a drug or metabolite in a specimen may not be subject to the same testing level criteria that were used during the original analysis. Some analytes deteriorate or are lost during freezing and/or storage.

I. <u>SECURITY</u>

The approved laboratory facilities shall use appropriate security measures to ensure limited and/or controlled access.

J. SUBCONTRACTING

The approved laboratory facility shall perform all work with its own personnel and equipment unless otherwise authorized by the Employer. The approved laboratory facility may either be an Employer facility or a privately owned facility under contract with the employer.

K. DOCUMENTATION

Documentation of all aspects of the testing process must be available. This documentation will be maintained for at least two years and will include: personnel files on analysts, supervisors, directors, and all individuals authorized to have access to specimens; chain of custody documents; quality assurance/quality control records; all test data; reports; performance records on proficiency testing; performance on accreditation inspections; and hard copies of computer generated data.

L. REPORTS

All test results, including initial, alternate retest, confirmation, and quality control data must be reviewed by the certifying scientist or laboratory director before a test result is certified as accurate. The report shall identify the drugs/metabolites tested for, whether positive or negative, and the threshold concentration for each.

M. <u>INSPECTIONS</u>

The Employer shall reserve the right to inspect the approved laboratory facility at any time. Contracts with laboratories, as well as for collection site services, shall permit unannounced inspections. Pre-award inspections and evaluation of the procedural aspects of the program must be accomplished prior to the award of any

PERSONNEL MANUAL

C 28.17

contract.

V. APPROVED LABORATORY FACILITY PERSONNEL AND QUALITY CONTROL REQUIREMENTS

A. LABORATORY PERSONNEL

The scientific director of the approved laboratory facility shall meet three criteria. He or she must: (1) (a) be certified as a Laboratory Director by the State in forensic/toxicological analysis, or (b) hold a Ph.D. in pharmacology, toxicology, or analytical chemistry; (2) have at least two years experience in analytic toxicology (the analysis of biological materials for drugs of abuse) and appropriate training and/or forensic applications of analytic toxicology (court testimony, research and publications in analytic toxicology of drugs of abuse, etc.): and, (3) have documented scientific qualifications comparable to those of a person certified by the American Board of Forensic Toxicology or the American Board of Clinical Chemistry in Toxicological Chemistry. The director is responsible for ensuring that there are sufficient personnel with adequate training and experience to supervise and conduct the work of the urine drug testing laboratory.

A key individual in the laboratory is the certifying scientist (who may be the Laboratory Scientific Director); this individual reviews the standards, control specimens, and quality control data together with the initial, alternate retest, and confirmation test results. After having assured that all results are acceptable, this individual certifies the test result. The certifying scientist must have sound training in the sciences, specific training in the theory and practice of the procedures used, including the recognition of aberrant results, and familiarity with quality control procedures.

Supervisors of analysts must possess a B.S. degree in chemistry or at least the education and experience comparable to a Medical Technologist certified by the American Society of Clinical Pathologists, MT(ASCP), or its equivalent. These individuals also must have training in the theory and practice of the procedures used, and understanding of quality control concepts. Periodic verification of their skills must be documented. Other technicians or nontechnical staff must possess the necessary training and skills for the task assigned. In-service continuing education programs to meet the needs of all laboratory personnel are desirable. Personnel files must include: resume of training and experience, certification or license, if any, references, job descriptions, health records,

PERSONNEL MANUAL

C 28.18

records of performance evaluation and advancement, incident reports, and results of tests for color blindness.

B. QUALITY ASSURANCE AND QUALITY CONTROL

Approved laboratory facilities shall have a quality assurance program which encompasses all aspects of the testing process: specimen acquisition, chain of custody, security, and reporting of results, in addition to the screening and confirmation of analytical procedures. Quality control procedures will be designed, implemented, and reviewed to monitor the conduct of each step of the process.

1. Requirement of Internal Laboratory Quality Control

As an internal laboratory quality control, laboratories are responsible for assuring that Quality Control (QC) urine specimens containing no drug and specimens fortified with known standards be analyzed with each run of specimens screened.

Implementation of procedures must be documented to ensure that carry-over does not contaminate the testing of a subject's specimen. The known standards shall be the first specimens processed in each run. After acceptable values are obtained for the known standards, those values will be used to calculate sample data.

2. Department External Laboratory Quality Control Procedures

Participation in proficiency testing surveys, by which the laboratory performance is compared with peers and reference laboratories, is encouraged. <u>Participation in a ADAMHA/National Institute on Drug Abuse (NIDA) recognized accreditation and proficiency testing program for drugs of abuse is mandatory.</u>

As an external laboratory quality control, the Employer's physician may submit to the approved laboratory facility for testing blank specimens (i.e. certified by the Employer's physician to contain no metabolites) or specimens of a known quantity. The blank or known quantity specimens submitted by the Employer's physician should appear to be normal samples to laboratory personnel. Any unsatisfactory proficiency testing result must be investigated by the Employer's physician and corrective actions must be taken. A report of the investigative findings, together with subsequent corrective actions, should be recorded, dated, signed by the responsible

C 28.19

supervisor and laboratory director and sent to the Employer's physician and the Employer's contracting officer. Should a false-positive error occur on a blind proficiency test specimen, retesting of all available specimens submitted to that laboratory for the period two weeks prior to the detected error and two weeks after is required. Unsatisfactory performance on proficiency test samples is sufficient cause for the Employer to revoke laboratory approval.

VI. REVIEW OF RESULTS

A. MEDICAL REVIEW OFFICER

An essential part of the drug screening program is the final review of results. A positive test result does not automatically identify an applicant as an illegal user of drugs. An individual with a detailed knowledge of possible alternate medical explanations <u>must</u> be involved in the review process. This review will be performed by the Employer's designated Medical Review Official (MRO) prior to the transmission of results to the department.

The MRO shall be a licensed physician with knowledge of substance abuse disorders. The role of the MRO is to review and interpret positive test results obtained through the testing program. In the conduct of this responsibility, the MRO should undertake the examination of alternate medical explanations for a positive test result. This action could include the conduct of medical interviews, review of the applicant's medical history, or the review of any other relevant biomedical factors. The MRO is required to review all medical records made available by the tested applicant when a confirmed positive test could have resulted from legally prescribed medication. After the MRO has reviewed the pertinent information and the laboratory assessment is verified, the case will be referred as determined by policy to the requesting department for disposition. Should any question arise as to the veracity of a positive test result, the MRO is authorized to order a reanalysis of the original sample. If the MRO determines there is a legitimate medical explanation for the positive test result, the MRO may deem that the result is consistent with legal drug use and take no further action. Additionally, the MRO, based on review of inspection reports, QC data, multiple samples, and other pertinent results may deem the result scientifically insufficient for further action and declare the individual as negative. The approved laboratory facility must be able to provide information to assist in this review process by

C 28.20

employing or having available a forensic toxicologist or someone with equivalent forensic experience in urine drug testing who can be called on when specific consultation is required by the MRO.

B. PROTECTION OF EMPLOYEE RECORDS

Any laboratory contract shall provide that the contractor's records are subject to the Uniform Information Practices Act (Modified). Hawaii Revised Statutes Chapter 92F. The Employer shall establish a system of records (or modify an existing system) to cover both the Employer's physician and the approved laboratory facility's records of employee urinalysis results. The contract and the system must have specific provisions that require that applicant records are maintained and used with the highest regard for the applicant's privacy.